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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/540,466 | 03/31/2000 | UGO RIPAMONTI | STK-6 | 2489 |
| 1473 | 7590 | 01/09/2004 | EXAMINER | |
| FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105 | | | NICKOL, GARY B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | |

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/540,466

Applicant(s)

RIPAMONTI ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/03/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,26,29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Response to Amendment

Re: Ripamonti *et al.*

Date of priority: March 31, 2000.

The Amendment filed November 3, 2003 in response to the Office Action of August 1, 2003 is acknowledged and has been entered.

Claims 1-20, 22-25, 27-28 are cancelled.

Claims 21, 26, and 29 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 21, 26 and 29 remain rejected under 35 U.S.C. 102(b) as being anticipated by Israel *et al.* (WO 93/09229, IDS) for the reasons of record in the Action mailed August 1, 2003, pages 7-8.

Applicants argue that the reference does not anticipate the claimed invention because Israel merely discloses the use of heterodimeric BMP-7 (also known as OP-1) for treating bone defects and wound healing and does not disclose a method of inducing angiogenesis comprising the step of administering a heterodimeric OP-1 or amino acid variant thereof. This argument has been considered but is not found persuasive as it appears that applicants have not considered the

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totality of the previous rejection which held that while Israel *et al.* do not characterize BMP-7 as angiogenic, the claimed functional limitation would be an inherent property of the referenced method since the specification teaches (page 2, line 15) that various physiological processes *require* angiogenesis, including wound healing and bone repair. Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. Furthermore, applicant's arguments appear to address a species of OP-1 (the heterodimeric species) which is not currently claimed, e.g. homodimeric. If it was applicant's intention to argue that Israel *et al.* only teach the heterodimeric species as opposed to the currently claimed homodimeric species, it should be recognized that the specification teaches that OP-1 is bioactive as a heterodimer or a homodimer. Furthermore, the teachings of Israel *et al.* encompass both homodimeric and or heterodimeric species of BMP-7 (OP-1) polypeptides. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Rejections:

Claims 21, 26, and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record with regards to the rejection of Claim 27 as set forth in the Office Action of August 1, 2003 (pages 3-5).

Applicants argue (pages 5-6) that the specification provides an adequate written description for variants of OP-1 wherein the specification at page 17, lines 8-16 describes that

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variants include those containing sequences that share at least 70% amino acid homology with the C-terminal seven cysteine domain of hOP-1. Applicants further argue that the specification clearly describes what is intended by 70% amino acid sequence homology. These arguments have been carefully considered but are not found persuasive. The claims are not limited to those variants that share at least 70% homology with the C-terminal seven cysteine domain of hOP-1. Rather, the claims are broadly drawn to administering an effective amount of any amino acid variant of a homodimeric OP-1. Thus, as set forth previously, the claims are drawn to a genus of amino acid variants that includes any and all alleles of OP-1. Since the specification only discloses one allele with the scope of the claimed genus, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of said genus is not representative of the variants of the genus and is therefore insufficient to support the claim. Only the dimeric species consisting of OP-1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 29 recites the limitation "the OP-1" in Claim 21. There appears to be insufficient antecedent basis for this limitation from which claim 29 depends because Claim 21 refers to *homodimeric OP-1*.

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All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN

January 8, 2004

A handwritten signature in cursive script, appearing to read "Gary B. Nickol".